REMARKS

Favorable reconsideration and allowance of the present application is respectfully requested.

In the Office Action, a restriction requirement was placed on the original claims. Specifically, restriction was required between claims 1-17 (Group I); 18-25 (Group II); 26-30 (Group III); 31-38 (Group IV); 39-42 (Group V); and 43-45 (Group VI). Applicants provisionally elected to prosecution the claims of Group II, and hereby affirm this election.

Currently, claims 46-61, including independent claim 46, are pending in the present application. For example, independent claim 46 is directed to a method for detecting the presence of a proteinase enzyme in a chronic wound of a human or an animal. The method comprises collecting a sample of fluid from the chronic wound of the human or the animal. The sample is exposed to a signal element bound to a target antibody, the target antibody being bindable to the proteinase enzyme to form a proteinase enzyme/target antibody complex. The proteinase enzyme/target antibody complex is exposed to a capture antibody to form a proteinase enzyme/target antibody complex/capture antibody conjugate. The proteinase enzyme is identified by determining the presence or absence of a detectable or measurable manifestation of the signal element. This identification allows for the selection of a treatment for the chronic wound that is effective for treating the identified proteinase enzyme.

In the Office Action, independent claim 18 was initially rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Specifically, the Office Action asserts that it is unclear whether the signal element is bound to the target antibody. Without

commenting on the propriety of this rejection, Applicants simply note that the present claims clarify that the signal element is bound, either directly or indirectly, to the target antibody. For example, in one embodiment, the signal element and target antibody are attached to a particle.

Besides the above-mentioned rejection, original independent claim 18 was also rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,736,341 to Sorsa, et al. Sorsa, et al. is directed to a method and test kit for diagnosing periodontal disease. Specifically, monoclonal antibodies are used to recognize the active form of mammalian MMP-8 and differentiate between the active and proenzyme forms. Sorsa, et al. also describes exemplary test kits for diagnosing periodontal disease. (See e.g., Cols. 21-22). However, the method for diagnosing "periodontal disease" taught in Sorsa, et al. does not disclose the presently claimed method for detecting the presence of a proteinase enzyme in a chronic wound of a human or an animal. For example, as noted above, the present claims require the step of "collecting a sample from the fluid of a chronic wound", and then identifying the proteinase enzyme in such a fluid.

Chronic wounds are characterized by an increase in the activity of proteinase enzymes (e.g., MMPs). These enzymes are responsible for the continued degradation of newly formed basal extracellular matrix (ECM). The stable formation of this matrix marks a committed entry into the healing process; however, constant ECM turnover results in an inability of the chronic wound to heal. Under normal circumstances, MMPs are prevented from destroying the wound bed by the action of tissue inhibitors of metalloproteinases (TIMPs). In chronic wounds, however, the ratio of MMP to TIMP is

high, such that most of the MMPs are uninhibited. In fact, with elevated proteinase enzyme levels, the TIMP molecules themselves can be hydrolyzed. (Appl. pp. 1-3).

As such, chronic wounds may be treated with inhibitory agents. Unfortunately, no naturally occurring TIMP molecule is known that inhibits all types of MMPs. TIMPs instead form inhibitory complexes with only a specific subset of MMPs. Thus, for therapeutic purposes, it is desirable to specifically identify which proteinase enzyme is present in the chronic wound. Further, because the levels of the proteinase enzymes are constantly in flux within a chronic wound, it is also desirable to identify the proteinase enzyme in the *current* condition of the chronic wound. (Appl. pp. 1-3).

In this regard, the presently claimed invention provides for a fast, accurate, and inexpensive method for identifying the proteinase in the chronic wound fluid. Such rapid detection allows for immediate treatment with an inhibitory agent that is specific for the identified proteinase enzyme. Advantageously, the inhibitory agent that is specific for the identified proteinase may be used to treat the *current* condition of the wound, without having to wait several days for the result. Sorsa, et al. simply fails to disclose the claimed method of identifying the presence of a proteinase enzyme in a "chronic wound." Thus, for at least the reasons set forth above, Applicants respectfully submit that the present claims patentably define over Sorsa, et al.

Original independent claim 18 was also rejected in the Office Action under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,143,506 to Golub, et al. However, Golub, et al. suffers from the same deficiencies noted above with respect to Sorsa, et al. That is, Golub, et al. is directed to a method for diagnosing periodontal disease, but fails to disclose the claimed method for identifying the presence of a

proteinase enzyme in a "chronic wound." For at least this reason, Applicants respectfully submit that the present claims patentably define over Golub, et al.

Furthermore, original independent claim 18 was also rejected in the Office Action under 35 U.S.C. §102(b) as being anticipated by the Maliszewska, et al. article, which is entitled "Development of an Ultrasensitive Enzyme Immunoassay for the Determination of Matrix Metalloproteinase-9 (MMP-9) Levels in Normal Human Cerebrospinal Fluid." As an initial matter, Applicants note that Maliszewska, et al. does not appear to have been published more than one (1) year before the filing date of the present application. Accordingly, Maliszewska, et al. does not constitute prior art to the present application under 35 U.S.C. §102(b). Nevertheless, even if certain subject matter of Maliszewska, et al. were considered "prior art" to the present application, Applicants respectfully submit Maliszewska, et al. still fails to disclose one or more limitations of the present claims.[1] For example, as with Sorsa, et al. and Golub, et al., Maliszewska, et al. also fails to disclose the claimed method for identifying the presence of a proteinase enzyme in a "chronic wound."

In addition to the rejections set forth above, the Original Declaration was objected to because one of the inventor's name had been changed from "Tyrell" to "Tyrrell" without an appropriate initial. In response to the Examiner's request, Applicants are submitting herewith Supplemental Declarations that include the correct spelling of the inventors' names. The Abstract was also objected to for various grammatical reasons. Applicants respectfully submit that the amendment set forth herein fully obviates this

[1] Applicants in no way acquiesce to the status of Maliszewska, et al. as "prior art" to the present application under any applicable section of 35 U.S.C. §102.

objection. Finally, the Figures were objected to for not containing a legend that defines numbers 1-4 and 13 in Figure 1. Applicants note, however, that such numbers are clearly defined in the present application. (See e.g., Appl. p. 6, ll. 10-18).

As such, at least for the reasons set forth herein, Applicants respectfully submit that the present application is in complete condition for allowance and favorable action, is therefore requested. Examiner Swope is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

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